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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/800,917

03/16/2004

Gertrud Hotten

2923-609

2179

6449

7590

01/09/2009

ROTHWELL, FIGG, ERNST & MANBECK, P.C.

1425 K STREET, N.W.

SUITE 800

WASHINGTON, DC 20005

EXAMINER

ROMEO, DAVID S

ART UNIT

PAPER NUMBER

1647

NOTIFICATION DATE

DELIVERY MODE

01/09/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No. 10/800,917	Applicant(s) HOTTEN ET AL.	
	Examiner David S. Romeo	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-17 is/are pending in the application.
- 4a) Of the above claim(s) 8,9,12 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6,7,10,11 and 14-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 6-17 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed 09/30/2008 has been entered. Claims 6–17 are pending.

Applicant's elected group I, claims 6–7 and 10–15, drawn to methods of treatment comprising administering MP52, in the reply filed on 01/09/2007. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 8–9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 01/09/2007.

Applicant's elected the species treatment of skin in the reply filed on 05/18/2007. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 12–13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 05/18/2007.

Maintained formal matters, objections, and/or rejections:

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 11 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Celeste

(5,658,882) as evidenced by Yamashita (Exp Cell Res. 1997 Aug 25;235(1):218-26).

Applicants argue that the claims are supported by the priority document filed on 08/10/1993. Applicants' arguments have been fully considered but they are not persuasive.

Although the priority document P 43 26 829.3 supports angiogenesis, it does not support the recitation of a "matrix." Therefore Celeste qualifies as prior art.

New Formal Matters, Objections and/or Rejections

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10, 11 and 14–17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a biologically functional part of SEQ ID NO: 2, wherein said biologically functional part has osteoinductive capability, does not reasonably provide enablement for a biologically functional part of SEQ ID NO: 2, wherein said biologically functional part has tissue inductive capability or mitogenic capability. The specification does not

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enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are directed to or encompass a biologically functional part of SEQ ID NO: 2, wherein said biologically functional part has tissue inductive capability or mitogenic capability.

5 The claims are construed as encompassing any and/or all tissue inductive capabilities or mitogenic capabilities. Therefore, the claims encompass biologically functional parts that regenerate tissues comprising permanent cells that are retained throughout adult life and seem never to divide and which cannot be replaced if lost, such as almost all nerve cells. See Alberts (Molecular Biology of the Cell, 1994), page 1142, last full paragraph. Although most permanent
10 cells renew their parts (See Alberts, pages 1144-1145), the claims encompass biologically functional parts that regenerate permanent cells, which cannot be replaced if lost. The specification lacks working examples of, and guidance for, the regeneration of permanent cells, which cannot be replaced if lost. There is lack of predictability in the art. See, for example, Nathan (Journal of Cell Biology, (1991 Jun) 113 (5) 981-986) wherein it is taught that given the
15 amino acid sequence of a cytokine and any of its actions one cannot predict when or where it will do what else (page 981, paragraph bridging columns 1-2). See also Hill (J Cell Physiol 1986 Aug;128(2):322-8) wherein it is taught that TGF- β 1 stimulates the growth of fibroblasts from very early human fetuses, but inhibits the growth of fibroblasts derived from fetuses of somewhat later gestational age (Abstract).

20 In view of the breadth of the claims, the lack of direction and working examples provided by the inventor, and the unpredictability in the art it would require undue experimentation for the skilled artisan to make and/or use the full scope of the claimed invention.

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Claims 6 and 7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating damage to bone, cartilage connective tissues, skin, mucous membranes and epithelium, or for a method of improving wound healing and tissue regeneration of connective tissues, skin, mucous membranes, bone, cartilage and epithelium, does not reasonably provide enablement for a method of treating damage to teeth, or for a method of improving wound healing and tissue regeneration of teeth. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are directed to or encompass the regeneration of teeth. However, "...there is no known method to regenerate large amounts of tooth structure." After a tooth has been damaged or destroyed, restoration of the missing structure can be achieved with restorations created from a variety of materials, including glass ionomer, amalgam, gold, porcelain, and composite. See the Wikipedia entry for "Tooth," §§ "Caries" and "Restorations." However, there do not appear to be any provisions for restoring a damaged or destroyed tooth with a cytokine, such as MP52.

The specification lacks guidance for, and working examples of, the restoration of large amounts of tooth structure.

In view of the breadth of the claims and the lack of direction and working examples provided by the inventor, it would require undue experimentation for the skilled artisan to make and/or use the full scope of the claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

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improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 6, 7, 10, 11 and 14–17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18, 19, 22–24, 26 and 27 of copending Application No. 11/545,480 in view of Yamashita (Exp Cell Res. 1997 Aug 25;235(1):218-26). Each set of claims is directed to the treatment of overlapping genera of conditions with overlapping genera of MP52 compounds. The induction of angiogenesis with MP52 is generic to the treatment of connective tissue with MP52, as evidenced by Yamashita (Abstract).

This is a provisional obviousness-type double patenting rejection.

Conclusion

No claims are allowable.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 9:00 A.M. TO 5:30 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, MANJUNATH RAO, CAN BE REACHED AT (571)272-0939.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE CENTRAL FAX NUMBER FOR OFFICIAL CORRESPONDENCE, WHICH IS (571) 273-8300.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

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ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING MAY BE OBTAINED FROM THE PATENT APPLICATION INFORMATION RETRIEVAL (PAIR) SYSTEM. STATUS INFORMATION FOR PUBLISHED APPLICATIONS MAY BE OBTAINED FROM EITHER PRIVATE PAIR OR PUBLIC PAIR. STATUS INFORMATION FOR UNPUBLISHED APPLICATIONS IS AVAILABLE THROUGH PRIVATE PAIR ONLY. FOR MORE INFORMATION ABOUT THE PAIR SYSTEM, SEE [HTTP://PAIR-DIRECT.USPTO.GOV](http://PAIR-DIRECT.USPTO.GOV). CONTACT THE ELECTRONIC BUSINESS CENTER (EBC) AT 866-217-9197 (TOLL-FREE) FOR QUESTIONS ON ACCESS TO THE PRIVATE PAIR SYSTEM,

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/DAVID S ROMEO/
PRIMARY EXAMINER, ART UNIT 1647

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DSR
JANUARY 5, 2009